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TITLE OF INVENTION APPARATUS AND METHODS FOR MEDICAL DIAGNOSTIC AND FOR MEDICAL GUIDED INTERVENTIONS AND THERAPY				
APPLICANT(S) FOR DO/EO/US SEGALESCU, Victor, and PALTELLI, Yoav				
<p>Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:</p> <ol style="list-style-type: none"> <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. <input checked="" type="checkbox"/> This is an express request to promptly begin national examination procedures (35 U.S.C. 371(f)). <input type="checkbox"/> The US has been elected by the expiration of 19 months from the priority date (PCT Article 31). <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ol style="list-style-type: none"> <input checked="" type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). <input type="checkbox"/> has been communicated by the International Bureau. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)). <ol style="list-style-type: none"> <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). <input type="checkbox"/> have been communicated by the International Bureau. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. <input type="checkbox"/> have not been made and will not be made. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). <input type="checkbox"/> An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). <p>Items 11. to 16. below concern document(s) or information included:</p> <ol style="list-style-type: none"> <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. <input type="checkbox"/> A FIRST preliminary amendment. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment. <input type="checkbox"/> A substitute specification. <input type="checkbox"/> A change of power of attorney and/or address letter. <input checked="" type="checkbox"/> Other items or information: 1) Postcard 				

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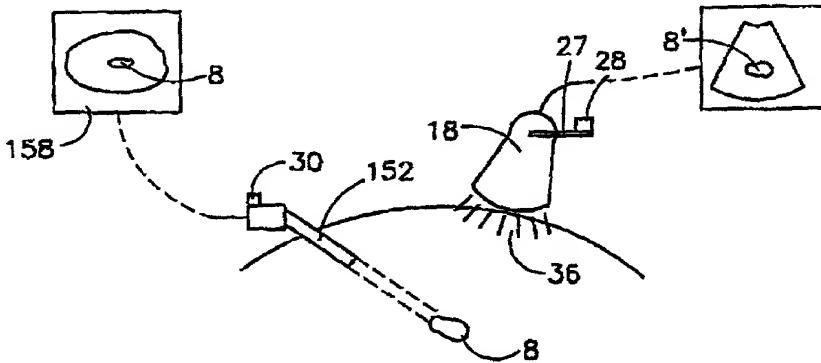
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(54) Title: APPARATUS AND METHODS FOR MEDICAL DIAGNOSTIC AND FOR MEDICAL GUIDED INTERVENTIONS AND THERAPY



(57) Abstract: The apparatus, and methods introduced in the present invention are enabled to measure the relative position between different medical imaging devices (18)(152), between the image planes, and/or image volumes produced by them by means of using a position measuring system based with attachable position measuring components (28)(30). This facilitates image fusing when images of the same plane/volume are available from different medical imaging systems. Additionally/alternately it enables to position a second medical imaging device over a desire area/volume according to information received from the image produced by the first medical imaging device.

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**APPARATUS AND METHODS FOR MEDICAL DIAGNOSTIC AND FOR
MEDICAL GUIDED INTERVENTIONS AND THERAPY**

CROSS REFERENCES TO RELATED APPLICATIONS

This PCT Patent Application is related to and claims priority from commonly
5 owned U.S. Provisional Patent Application No. 60/ 127,267 filed on March 31, 1999
entitled:

**' APPARATUS AND METHODS FOR MEDICAL DIAGNOSTIC AND FOR
MEDICAL GUIDED INTERVENTIONS USING MULTIPLE IMAGING
SYSTEMS.**

10 This Provisional Patent Application is incorporated by reference in its entirety
herein.

FIELD OF THE INVENTION

The present invention relates to apparatus for performing medical diagnosis,
and to apparatus for planning and performing medical interventions or therapy
15 procedures. Particularly, the present invention is related to apparatus for performing
guided medical interventions or medical therapy procedures that employ multiple
medical imaging systems for viewing the target in a body or body volume during the
intervention.

BACKGROUND OF THE INVENTION

20 During recent years fusing images from different medical imaging systems in
order to receive a better diagnostic has become widely used. Additionally, the
cooperative operation of several medical imaging devices can reduce the amount of

radiation at which patient is subjected during diagnosis, therapy planning and medical procedures and interventions. While these facts have been already recognized, the realization of such cooperative operation has been until now generally restricted to medical imaging devices having a common mechanical platform.

5 Additionally, various directional therapy procedures (based on directing an energy field towards a target in a body) are assisted by images of said body and target produced by medical imaging devices like CT, MR, ultrasound, etc.

SUMMARY OF THE INVENTION

During diagnosis during medical interventions or during therapy procedures, it may be necessary or helpful to operate several medical imaging devices simultaneously or sequentially. This is done upon necessity and compatibility between the devices, in 5 order to indicate the condition of the patient and/or designate a target in a body or body volume. For example the same target can be viewed by ultrasound and by some other medical imaging device such as a CT, X-Ray, or endoscope imaging device.

The present invention comprises methods and apparatus for combining two or more medical imaging systems (such as an ultrasound and a CT) in medical diagnosis 10 and procedures without mechanical constrains between the position of the two or more medical imaging devices. The present invention is particularly useful in guided medical interventions into a body or body volume, where a target is sought to be evaluated. The apparatus disclosed in the present invention comprises at least two medical imaging devices for example, an ultrasound, CT, X-Ray, endoscope, at least a display, 15 a data processor, and a position measuring system comprising position controlling and position measuring components. At least part of the position measuring components are located at determined positions with respect to the medical imaging devices and calibrated with respect to the image\beam produced by the imaging devices. The position measuring system enables the establishment of the relative positions between 20 the at least two medical imaging devices. The data processor receiving the information from the position measuring system, is also able to establish the position between the image planes/volumes produced by the at least two imaging devices and using it for at least one of the following:

- a) maneuvering one or more imaging devices in order to scan the interest target within the body according to information available from another medical imaging device, or
- b) facilitating image fusing when images of same plane/volume are available

5 from two or more imaging devices.

The term position measuring components defines any of the following group: transmitter or receiver or reflector or transceiver or optical indicia or inertial sensor or any combination of the above, suitable to be part of a position measuring system. This position measuring system may be magnetic, acoustic, optic, inertial or a combination
10 of the above.

The resultant apparatus enables free-hand manipulation of all or part of the medical imaging devices used in the same intervention or diagnosis.

The apparatus and methods described in the present invention facilitate the combination of a number of medical imaging devices to perform various medical
15 diagnostic, therapy procedures and intervention tasks more safely and efficiently than those of the conventional systems. Particularly, the apparatus of the present invention enabling viewing of a target with one medical imaging device and guiding a medical intervention tool or a medical therapeutic tool, or alternatively inserting a medical device when using a second medical imaging device. This can be particularly useful
20 when employing image guided medical intervention systems such as those introduced by the assignees in commonly assigned U.S. Patent No. 5,647,373, entitled: Articulated Needle Guide For Ultrasound Imaging And Method Of Using Same, and patent applications, PCT/IL96/00050 (WO 97/03609), entitled: Free-Hand Aiming Of

A Needle Guide; PCT/IL98/00578, entitled: System And Method For Guiding The Movements Of A Device To A Target Particularly For Medical Applications; and PCT/IL98/00631, entitled: Calibration Method And Apparatus For Calibrating Position Sensors On Scanning Transducers, all four of these documents incorporated by reference in their entirety herein.

The apparatus described in the present invention may also reduce the amount of radiation applied on a patient during diagnostic and medical interventions and/or therapy, for example when using ultrasound and CT in the same intervention.

The present invention also comprises methods and apparatus for guiding a directional therapy procedure without mechanical constrains between the position of the medical imaging device or devices used to assist the therapy procedure and the directional therapeutic device. The apparatus therefore, enables free-hand manipulation of part or all of the medical imaging devices used to assist the therapy procedure and/or of the therapeutic head. The term directional therapy procedure will define any procedure during which an energy field is directed towards a target or area in the body of the patient. This energy field can be ultrasonic or shockwaves (lithotripsy) , or electromagnetic (radiotherapy, laser, etc) or particle beam (proton beam for example). The data processor receives the information from the position measuring system and uses it for directing the therapy device head/beam towards a desired target in the body.

The method and apparatus are beneficial in that they have add-on capabilities; can define dynamic architectures, and enable free-hand maneuvering of all or part of the devices employed therein.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will now be described by way of the accompanying drawings, wherein like reference numerals and/or characters indicate corresponding or like components. In the drawings:

FIG. 1a pictorially illustrates one form of a system constructed according in accordance with the present invention for cooperative operation of an ultrasound and a computerized topography (CT) apparatus;

FIG. 1b pictorially illustrates the relative position between the scanning beams of the CT and ultrasound in FIG. 1a;

FIG. 2a is a vector diagram which pictorially illustrates the vectors used in calculating the relative position between the scanning beams of the ultrasound and the CT in FIG 1a;

FIG. 2b is a block diagram illustrating the steps involved in calculating the relative position between the scanning beams of the ultrasound and the CT in FIG 1a.;

FIG. 3 pictorially illustrates display functions enabled according to the present invention in relation to FIG. 1a.;

FIG. 4 is a simplified flowchart illustrating the steps of using in a cooperative mode two medical scanning devices in accordance to the present invention;

FIG. 5a pictorially illustrates one possible position measuring system to be used in accordance to the present invention;

FIG. 5b pictorially illustrates another possible position measuring system to be used in accordance to the present invention; and

FIG. 6 pictorially illustrates one form of a system constructed according in accordance with the present invention for cooperative operation of an ultrasound and a X-Ray:

DETAILED DESCRIPTION OF THE EMBODIMENTS

FIG. 1a illustrates a first embodiment, exemplary of the present invention. The first embodiment utilizes at least two compatible medical imaging devices that produce medical images. Here, the medical imaging devices include an ultrasound apparatus 2, 5 and a computerized tomography (CT) apparatus 4, employed in a cooperative operation. Alternately, the medical imaging devices could be the same or different devices, or combinations thereof, provided they operate cooperatively with respect to each other and are compatible. For example, these devices may be devices that produce images by ultrasound, computerized tomography (CT), X-ray, endoscopy etc.

10 In the set-up illustrated in Fig. 1, for example, images produced by CT 4 of a body 6 (or body volume) of a target 8 in the body 6 (body volume) may be utilized to position ultrasound transducer 18 at known position with respect with respect to target 8, even if target 8 cannot be imaged as accurately by ultrasound. This is particularly useful in CT assisted medical interventions enabling to use ultrasound images for 15 real-time monitoring of the invasive tool while using the CT images for primary location of the target. Additionally, images produced by the two medical imaging devices may be combined in real-time or off-line to produce the detail required in the area of the image required. This may also be used for monitoring anatomic changes due to breathing or internal movements between the CT images and the situation of the 20 body 6 at the time of the procedure. The system can be fitted to existing and deployed medical imaging devices without major modifications or adaptations.

Ultrasound 2 and/or CT 4 are connected to a display 10 via an image processor 12 (optional) contained in data processor 14, for displaying on display 10 at least the

images produced by ultrasound 2 and CT 4. Ultrasound 2 and/or CT 4 can also be connected directly to display 10 via the necessary connections and hardware. Image processor 12 can be part of the data processor 14 or can be connected to it.

Ultrasound 2 comprises a main unit 17 connected to a scanning head 18 further referred to as the ultrasound transducer as is known in the art. CT 4 comprises a main unit (CT computer) 20 connected to a scanning head 22, further referred to as a CT scanning head. CT scanning head 22 includes X-ray emitter and detector(s) (not shown) as is known in the art. The term scanning head will be used to define the detector and/or emitter component of the medical imaging or scanning device, such as the transducer of an ultrasound, or the X-ray emitter and detector(s) of a CT or an X-ray or the CCD of an optical endoscope.

A position measuring system comprising at least a position sensing controller 26 and position measuring components (PMCS) 28, 30, 32 and 34 is used to measure the relative position between ultrasound transducer 18 and the CT scanning head 22. The term position measuring components will define any of the following group: transmitter or receiver or reflector or transceiver or optical indicia or inertial sensor or any combination of the above, suitable to be part of a magnetic (for example, in accordance with the systems detailed in U.S. Patents Nos. 4,314,251, 4,054,881) or acoustic (for example, in accordance with the system detailed in U.S. Patent No. 4,124,838) or optic (for example, in accordance with the system detailed in U.S. Patent No. 4,649,504) or inertial (for example, IS900 manufactured by InterSense Inc.) position measuring system or any combination of the above, all of the above listed U.S. Patents incorporated by reference herein. Also, position levers in

accordance with U.S. Patent No. 5, 647, 373 and PCTs PCT/IL96/ 00050, PCT/IL98/ 00578, PCT/IL98/ 00578 and PCT/IL98/ 00631, listed above, are also suitable. Position sensing controller 26 can be part of the data processor 14.

In order to perform the task of measuring the relative position between 5 ultrasound transducer 18 and CT scanning head 22, position measuring component 28 is attached at a known and fixed position with respect to the ultrasound transducer 18. The attachment can be either directly to the transducer 18 or by means of an extension 10 27. Position measuring component 28 is calibrated to ultrasound transducer 18 such that the ultrasound beam 36 is at a known and fixed position with respect to position measuring component 28. Such calibration can be achieved by operating according to 15 PCT application PCT/IL98/00631.

Position measuring component 30 is attached at a known and fixed position from CT scanning head (gantry) 22. The attachment can be either directly to the CT scanning head (gantry) 22 or by means of an extension 29. The term position defines 15 location and/or orientation.

Position sensing controller 26 measures the relative position between position measuring component 28 and position measuring component 30, enabling to calculate the relative position between ultrasound transducer 18 and CT scanning head 22. Position measuring component 30 is calibrated to scanning head 22 such that the CT 20 scanning beam 34 is at a known and fixed position with respect to position measuring component 30. Such calibration can be achieved by operating according to the co-assigned PCT application PCT/IL98/00631.

Reference is now made to FIG. 1b that shows a detailed view of ultrasound transducer 18, CT scanning head 22 and position measuring components 28 and 30. Items referred to in previous figures are numbered similarly and will not be further described.

5 Alternately/additionally position measuring component 32 may be attached to CT bed 15. The attachment can be either directly to the CT bed 15 or by means of an extension 31. In this case position measuring component 34 is attached at a fixed position with respect to a reference position of the CT scanning head 22 (for example the default perpendicular position), and movements of the gantry 22 are compensated
10 according to information available from the CT computer 20.

An additional position measuring component 34 may be attached at a fixed position from CT scanning head attached from the ceiling of the CT room by arm 33. In this case position measuring component 34 is attached at a fixed position with respect to a reference position of the CT (for example the default position), and
15 movements of the gantry 22 are compensated according to information available from the CT 20.

It is not necessary to use position measuring components 30, 32 34 together. Rather, it is sufficient to use at least one of them. In order to operate the apparatus properly it is sufficient to implement only one of the above position measuring
20 components 30, 32 and 34 in combination with position measuring component 28. Position measuring components 32 and 34, if used, are calibrated to CT scanning head 22 similar to the calibration of position measuring component 30, if used.

Since position measuring component 28 is calibrated to transducer 18 and at least one of the position measuring components 30, 32 and 34 is calibrated to CT scanning head 22 it is possible to calculate the relative position between ultrasound scanning beam 36 and CT scanning beam 38. This is calculated based on measuring the relative position between position measuring components 28 and at least one of the following: one of position measuring components 30, 32 and 34, and based on the calibration values defined above. The vector diagram of FIG. 2a and flowchart of FIG. 2b illustrate one possible algorithm to be used for calculating the relative position between the beams of the two medical imaging devices.

Reference to flowchart of FIG. 2b, block 40 shows the result of the calibrating position measuring component 28 to ultrasound transducer 18. Block 42 shows the result of the calibrating position measuring component 28 to ultrasound transducer 18. Blocks 40 and 42 are generally performed off-line. Block 44 shows the measurement of the relative position of position sensor 28 with respect to position sensor 30. Block 46 shows one possible set of equations (Equations 1 and 2 described below) for calculating the relative position between ultrasound scanning beam 32 and CT scanning beam 34. These equations are:

$$[M]_{CT_S_B}^{US_S_B} = [M]_{CT_S_B}^{P_M_C_30} * [M]_{P_M_C_30}^{P_M_C_28} * ([M]_{US_S_B}^{P_M_C_28})^T \quad (Eq. 1)$$

$$\vec{d}_{CT_S_B}^{US_S_B} = [M]_{US_S_B}^{P_M_C_28} * ([M]_{P_M_C_30}^{P_M_C_28})^T * \vec{d}_{CT_S_B}^{P_M_C_30} + \\ 20 \quad (Eq. 2)$$

$$[M]_{US_S_B}^{P_M_C_28} + \{ \vec{d}_{P_M_C_30}^{P_M_C_28} - \vec{d}_{US_S_B}^{P_M_C_28} \}$$

The indexes and parameters in the above equations are according to vector diagram of FIG. 2a and flowchart of FIG. 2b. It is therefore possible to calculate the

relative position of transducer 18 and ultrasound beam\image 36 with respect to a CT image or CT set of images.

Necessary correction due to moving the CT stretcher 16 outside the gantry can be performed according to information available from the CT system (the displacement of stretcher 16 can be measured with an accuracy of less than 1

5 0.25mm to 0.5 mm). The movement of the bed stretcher 16 can be at a predetermined value bringing the desired target 6 or CT slice of interest at the same position from CT scanning head (gantry) 22. Alternately, the CT stretcher 16 can be moved at any desired position.

10 Necessary correction due to tilt of the scanning head of the CT 22 may be performed according to information available from the CT system 4.

Necessary correction due to swivel of bed stretcher 16 can be performed according to information available from the CT system.

15 Necessary correction due to using oblique or perpendicular CT images can be performed according to information available from the CT system.

All the above mentioned correction values can be manually inputted to the data processor 14 or transferred through communication links from CT main unit 20 or data processor 14 can identify them automatically for example according to information generally available in the CT image (video or DICOM form).

20 Similar or alternate algorithms can be implemented in connection to position measuring components 32 and 34.

Referring to FIG. 3, the relative position of ultrasound image (scanning beam 34) with respect to a set of CT images is indicated to the operator on the apparatus

display 10. The indications are in 2-D and/or 3-D fashion for example in the form of boxes 60, 62, 64, 66 and 68.

The amount of deviation of ultrasound scanning beam 36 from a reference CT scanning image 38 can be displayed to the operator, for example in the form of angles and distances, as in box 60, and in the form of side-view illustration box 62, and top-view illustration, box 64. This enables the operator to first scan body 6 by CT, identify at least one target 8 in body 6, and then position ultrasound transducer 18 such as to view a desired CT slice\image.

Additionally, target 8 can be marked in a CT image and it is possible to maneuver ultrasound transducer 18 such as to view the target 8. The indications can be in the form of box 66 comprising arrows indicating how to maneuver transducer 18 and numbers indicating the distance of target 8 from ultrasound scanning beam 36. It is then possible, for example, to guide an invasive tool towards target 8 based on CT images in combination with real-time imaging of the invasive tool by ultrasound.

Boxes 68 and 70 provide information regarding the position transducer beam 36 with respect to a volume of CT images. Box 68 shows the CT slice (reconstruction) aligned with the current position of transducer 18. Box 70 illustrates the relative position of transducer 18 with respect to the scanned volume in a sagittal view.

While Fig. 3 illustrated specific display modalities for enabling the user to cooperatively use ultrasound 2 and CT 4 information additional or alternate displays may be used.

In applications requiring very high accuracy it may be necessary to constrain body 6 in order to avoid small movements between scanning body 6 by ultrasound 2 and scanning body 6 by CT 4. In most applications this requirement is not necessary.

Reference is now made to FIG. 4 which is a flow-chart illustration of the steps required in order to operate ultrasound 2 and CT 4 in operative cooperation as illustrated in Fig. 1 and in accordance to the present invention. At step 90, it is measured the relative position between position measuring components (PMC) 28 and 30 (FIG. 4). It is possible to use position measuring components 32 or 34 or both instead or in addition to position measuring component 30 (as explained above). At step 92 it is calculated the relative position between ultrasound scanning plane/volume/image 36 and CT scanning plane/volume/image 38. The calculation at step 92 is based on the calibration of position measuring component 28 and 30 (32, 34) with respect to ultrasound transducer 18 and CT scanner 22 (step 94). The calculation in step 94 may also be used in other medical procedures (step 96) that is optional, but preferred, for example in image guided interventions, such as described in commonly assigned U.S. Patent No. 5,647,373. The calculation in step 92 may also be used in order to instruct the maneuvering ultrasound transducer 18 in a required position. Once the relative position between the scanning planes/volume is calculated the images from CT system 4 and ultrasound system 2 may be correlated and or fused in optional, but highly preferred step 98. This can be performed according to conventional image processing algorithms and techniques. By correlating or fusing these images (from the ultrasound and CT scanning beams, respectively), the displayed ultrasound image may be enhanced. The superimposed image/information resulting of step 98 may be

optionally used to improve calculation at step 92 in an iterative mode. The superimposed image/information resulting of step 98 may also be used in other medical procedures (step 96) or in order to instruct maneuvering of ultrasound transducer 18 (step 120).

5 The imaging options 100 are non-exhaustively, listed as follows. The image from CT system 4 and ultrasound system 2 may be displayed individually (steps 102 and 104), the relative position between CT and ultrasound scanning beams may be displayed (step 106, illustrated in Fig. 3) and the result of image fusing, at step 98 may also be displayed (step 108). Target and image correlation information can also be 10 available to the operator indicating for example internal anatomic movements as explained herein below.

In addition to and interacting with display functions 100, there are various ancillary functions such as optionally marking a target 8 (step 112) on the image produced by one of the imaging devices as appearing on display 10. Then the position 15 of target 8 may be calculated within the scanning beam of the medical imaging device. (step 114). Additionally/alternately a reference plane/volume may be marked or signaled according to the image produced by one of the imaging device (step 116). The position of the reference plane/volume may then be calculated (step 118). The data in steps 114 and/or 118 may be optionally used in order to instruct the positioning of CT 20 scanning head 22 and ultrasound transducer 18 with respect to each other (step 120).

A specific implementation to be used in connection to the present invention regards the use of image correlation in applications where internal organs may significantly move between the time the CT scan was performed and the time of

performing a procedure. Body volume 6 is scanned by the CT system 4 producing high resolution image/information. The operator defines at least one target on CT image as displayed on display 10. The same target is then scanned with ultrasound transducer 18. The position of the ultrasound scanning beam\image 36 is determined (as detailed above) with respect to position of the CT scanning beam 38. Additionally, by comparing the relative position of target 8 in the ultrasound image with the position calculated from the CT image, it is possible to monitor and compensate for internal movements or for respiratory changes in body 8 between taking the CT scan and the time of performing an intervention. For this implementation it is preferred (but not necessary) to mark more than one target/points in the CT image and then locate them by ultrasound. This enables to calculate internal anatomic displacements inside body 8, between the images produced by the CT and the situation during the time of an intervention. The operation defined above can also be performed automatically provided enough distinctive targets\points\clusters may be found in the CT and ultrasound images.

Reference is now made to FIG. 5a that illustrates a magnetic position measuring system to be used in accordance with an exemplary embodiment of the present invention. Similar items in previous figures have similar numbers and will not be further described.

In this exemplary embodiment position measuring component 28 is a receiver 28' being attached to ultrasound transducer 18 and position measuring component 30 is a transmitter 30' being attached to CT scanning head 22 by an arm 80'. Transmitter 30' is transmitting AC or DC magnetic/electromagnetic signals to receiver 28'. The

output of receiver 28' is transmitted by wire or wireless connections to position sensing controller 26 enabling to calculate the relative position of receiver 28' with respect to transmitter 30'. Alternately, position measuring component 28 could be a transmitter and position measuring component 30 could be a receiver.

5 Reference is now made to FIG. 5b wherein an optical position measuring system is employed in accordance with another exemplary embodiment of the present invention. Similar items in previous figures have similar numbers and will not be further described. A stereo vision charge coupled device (CCD) camera 84' is positioned on an arm 86' at a first reference location. Position measuring component 10 28 includes a cluster of LED's 28'' being attached to ultrasound transducer 18 by an arm 88' and position measuring component 30 includes a cluster of LED's 30'' being attached to CT scanning head 22 by an arm 80''. The relative position of cluster of LED's 28'' is measured with respect to the CCD camera 84' (first reference location), and also the relative position of cluster of LED's 30'' is measured with respect to CCD 15 camera 84' (first reference location). It is therefore possible to calculate from the above measurements the relative position of cluster of LED's 30'' with respect to cluster of LED's 28'' and hence, the relative position between ultrasound scanning beam 32 and CT scanning beam 34.

20 The above detailed position measuring systems enable measurement of the relative position between ultrasound transducer scanning beam 32 and CT scanning beam 34 can be optical, acoustic, magnetic or inertial or a combination of the above. The relative position between position measuring components 28 and 30 can be measured directly, for example, when one of the components is a receiver and the

other one is a transmitter as illustrated in the exemplary embodiment in FIG. 5a.

Alternately, the relative position between position measuring components 28 and 30 can be calculated indirectly, for example, by measuring the position of each with respect to a reference location as illustrated in the exemplary embodiment in FIG. 5b.

5 When making these indirect calculations, a third position measuring component 84 (illustrated in FIG. 5b by a stereo Charge Coupled Device (CCD) 84') is in operative communication with position measuring components 28 and 30, this CCD 84 is positioned at a first reference location. The first reference location may be fixed and known. Alternately, the first reference position can be movable and unknown.

10 Optionally, the first reference position can be attached to the bed 24.

Position measuring components 28, 30 and 84 (if part of the system) may be any of the following group: transmitter or receiver or reflector or transceiver or optical indicia or any combination of the above. Position measuring components 28, 30 and 84 (if part of the system) may be part of a magnetic or acoustic or optic or inertial 15 position measuring system or a combination of the above.

Position sensing controller 26 may communicate with at least one or all of position measuring components 28, 30 and 84 (if part of the system) by wired or wireless links.

Reference is now made to FIG. 6, which illustrates an additional embodiment 20 of the present invention. Similar items to those shown in previous figures have similar numbers and will not further be described. The second embodiment illustrates an ultrasound 2, and an X-Ray 138 to be used in cooperative operation according to the present invention. The X-Ray imaging device comprises X-Ray main unit 140 and

X-Ray scanning head 142 including emitter 142' and detector 142'. X-Ray scanning head 142 is mounted on a movable and adjustable arm 144. Bed 24 may or may not be part of X-Ray imaging device 138.

Position measuring component 30 is attached at known and fixed positions from 5 X-Ray scanning head 142. Additionally, position measuring component 30 is calibrated to the scanning head 142 such that it is at a known position from the scanning volume of the X-Ray. Such calibrations can be achieved by operating according to patent application PCT/IL98/00631. The relative position between ultrasound transducer scanning beam 36 and the X-ray scanning volume 146 can be calculated as described 10 in the first embodiment based on direct measurement between position measuring components 28 and 30.

An additional position measuring component 84 can be placed at a reference location on an arm 86. This position measuring component 84 (if used) is in 15 cooperative communication with position measuring components 28 and 30. Thus, the position of ultrasound transducer 18 and of the X-Ray scanning head 142 are measured with respect to the reference position similar to the calculation described in relation to FIG. 5b. Body 6 can be fixed so as to avoid movement during the procedure. X-Ray scanning head 142 is positioned in order to view target 8 in the body 6 or body volume at two different positions. The position of X-Ray scanning head 142 is measured with 20 respect to reference position thus enabling to correlate the two images into stereo information in order to receive a 3D image of the scanned body 6. Algorithms for creating such 3D image/information from stereo 2D images/information are known to those skilled in the art.

In one exemplary use of present invention, the operator may indicate target 8 on the image received from the X-Ray 138 for example, by marking it with a mouse on the display 10 (as described herein above with reference to Figs. 1-3). The relative position of target 8 can be calculated with respect to the reference point. Ultrasound transducer 18 is then applied to body volume 6 and its position is measured with respect to the reference position. Thus, it is possible to calculate the position of ultrasound scanning plane 36 with respect to the image volume received from X-Ray 138 and target 8.

Alternately, the body volume 6 is first imaged by ultrasound in order to establish a desired reference plane/volume that includes a target 8. The operator selects a reference plane, in accordance with the procedures detailed above. Alternately, the operator indicates target 8 for example by marking it on the display 10, using conventional marking software, as described above. Data processor 14 stores the position of target 8 or of reference plane with respect to the reference location. Ultrasound transducer 18 is then removed and the position of X-Ray scanning head 142 is calculated with respect to reference plane or target 8. Thus, it is then possible to position X-Ray scanning head 142 in an optimal way at two different positions so as to view target 8 and afterwards produce a 3D image/information.

Additional modalities of employing in operative cooperation ultrasound 2 and X-Ray 138 are similar to those described for the system illustrated in Figs. 1a,4 and described above.

Reference is now made to FIG. 7a and 7b, which illustrate an additional embodiment of the present invention. Similar items to those shown in previous figures

have similar numbers and will not further be described. The second embodiment illustrates an ultrasound 2, and an optical endoscope 150 to be used in cooperative operation according to the present invention. Said endoscope 150 comprising an endoscope head 152 with a CCD 154 (not shown in the drawing) and optical apparatus 156 (not shown in the drawing). Endoscope head 152 can be rigid, or can be flexible. It is still possible to use a rigid endoscope head 152 with a mobile tip enabling to change the angle of view. It is also possible to use endoscope with changing field of view.

Position measuring component 30 is attached at a known position with respect to optical endoscope head 150 and calibrated to the endoscope image 158. Position measuring component 28 is attached at a known position with respect to transducer 18 and calibrated to transducer beam/image 36 as described above. If endoscope head 152 is rigid position measuring component may be attached internally or externally at any fixed position with respect to endoscope head 152. If endoscope head 152 is flexible or has a mobile tip, position measuring component 30 is positioned at the tip of head 150. An example of such position measuring component is the magnetic sensor manufactured by Mednetix Inc. Alternately, position component 30 can be a combination of two different functional sub-components. A first sub-component of positions measuring component 30 measuring the position of the head 152 at a default situation (default bending or default tip position). A second sub-component of position measuring component 30 being attached to the flexible part of endoscope head 152 (and preferably also to the tip) and providing indication with respect to the bending or movement of the flexible part with respect to said default situation. An illustrative

example for such a second sub-component could be a fiber optic sensor manufactured by Measurand Inc. Still alternately, in the case of a rigid endoscope with mobile tip it can be possible to receive from the endoscope information regarding the deviation from the default situation.

5 According to one aspect of the present invention target 8 is viewed by ultrasound transducer 18, and endoscope head 152 is maneuvered to view target 8 based on guiding information received from data processor 14 (not shown in Fig. 7) and displayed on display 10 (not shown in Fig. 7). The guidance can be in accordance to the methods introduced by the assignees in above cited patent applications

10 PCT/IL96/00050 or PCT/IL98/00578.

According to another aspect of the present invention target 8 is viewed by transducer 18 and also by endoscope head 152. It is then possible to mark target 8 in the ultrasound image and calculate its position with respect to position measuring component 28. According to the measured relative position between position measuring components 30 and 28 and based on the calibration of position measuring component 30 to the endoscope image 158 it is possible to calculate the 3D position of target 8 with respect to endoscope image 158. This enables to guide an invasive tool towards target 8 based on endoscope image 158 from any desired angle according to the method and apparatus described in above cited patent applications PCT/IL96/00050

15 or PCT/IL98/00578.

According to another aspect of the present invention it is possible to receive depth information from the endoscope image by alternative methods without the need to use transducer 18. According to one alternative method a target is viewed by

endoscope 150 while moving the endoscope head 150 at several positions on a straight line around the focussed position, at least one position providing a focussed image of the target. According to the focussing and de-focussing of the target and according to the measured position of position measuring component 30 it is possible to receive the 5 depth of the target in the endoscope image from algorithms known as "depth from focus". According to another method endoscope head 152 is viewing a volume of body 6 comprising target 8 from at least two different positions enabling to implement 3D stereo imaging. The implementation of the stereo imaging algorithm is based on knowing the relative position between the two or more positions of the endoscope head 10 152. According to still another method it is possible to receive the depth of a target 8 from methods known to those skilled in the art as "depth from shading". Such methods are described in US Patent No. 4,714,319 and US Patent No. 4,695,130

All the above described methods can provide 3D information regarding the 15 position of target 8 in the image produced by endoscope 150. It is therefore possible to attach an additional position measuring component to an invasive tool and guide it to target 8 assisted by endoscope imaging in accordance to the methods described in 20 guidance methods according to above cited patent applications PCT/IL96/00050 or PCT/IL98/00578.

While the invention has been described with respect to several preferred 25 embodiments, it will be appreciated that these are set forth merely for purposes of example, and that many variations, modifications and applications of the invention may be made. Accordingly, the scope of the invention is defined by the claims, which follow.

CLAIMS

1. A method enabling free of predefined mechanical constraints cooperative operation of two or more medical imaging devices useful in medical diagnosis and/or medical therapy planning and/or medical intervention planning and/or medical therapy and/or medical intervention and/or medical procedures, the method comprising the steps of:
 - imaging a body volume/plane with a first medical imaging device;
 - sensing the position of a second medical imaging device with respect to said first medical imaging device by means of a position measuring system comprising position measuring controller and position measuring components;
 - scanning part or all of said body volume/plane with said second medical imaging device;
 - calculating the relative position of said second medical imaging device and/or relative position of the scanning plane/volume produced by said second medical imaging device with respect to said first medical imaging device and/or with respect to the scanning plane/volume produced by said first medical imaging device;
 - displaying on at least one display screen said calculation in a cooperative way to the medical operator.
2. The method according to claim 1 where said first and said second medical imaging devices operate sequentially.

3. The method according to claim 1 where said first and said second medical imaging devices operate simultaneously and/or intermittently.
4. The method of claim 1 where said one first and said one second medical imaging device are one of the group X-Ray, CT, MRI or ultrasound, endoscope.
5. The method of claim 1 where the position measuring system is from the group: magnetic, optic, acoustic, inertial, fiber optic or a combination of the above.
6. The method of claim 1 where the step of sensing the position of second medical imaging device with respect to said first medical imaging device is performed by means of wired or wireless communication.
- 10 7. The method according to claim 1 where the position of the scanning plane/volume/image produced by said second medical imaging device is calculated with respect to the scanning plane/volume/image produced by said first medical imaging device.
- 15 8. The method according to claim 1 where the scanned plane/volume produced by said first medical imaging device is correlated and/or fused by image processing tools with the scanned plane/volume/image produced by said second medical imaging device.
- 20 9. The method according to claim 1 further comprising the step of indicating to said position sensing system the position of a target by marking said target on said at least one display screen or by automatic recognition of the target in the image.

10. The method according to claim 1 further comprising the step of indicating to said position sensing system the position of a reference plane/volume by marking said reference plane/volume on said at least one display screen.
11. The method according to any of the claims 9 or 10, where the position of the said second medical imaging device is calculated with respect to said target and/or said reference plane/volume/image.
12. The method according to claim 1 where the position of the scanning plane/volume produced by said one second medical imaging device is calculated with respect to said target and/or said reference plane/volume.
- 10 13. The method according to claim 1 and further comprising the step of indicating on said at least one display screen the actual progressive motion of said second medical imaging device towards said target and/or reference plane/volume.
14. The method according to claim 1 and further comprising the step of indicating on said at least one display screen the deviation of said second medical imaging device or scanning plane/volume produced by said second medical imaging device from said target and/or from said reference plane/volume.
- 15 16. The method according to claim 1 and further comprising the step of adjusting the position of said second imaging device so as to cause it to include in its scan plane/volume/image said target or to cause that its scan plane/volume coincide with said reference plane/volume.
- 20 17. The method according to claim 1 and further comprising the step of correlating the calculated position of at least one target or the relative position between several

targets/points in order to assess internal anatomic movements between different stages of a medical procedure.

17. Apparatus enabling free of predefined mechanical constraints cooperative operation of two or more medical imaging devices useful in medical diagnosis and/or 5 medical therapy planning and/or medical intervention planning and/or medical therapy and/or medical intervention and/or medical procedures, apparatus comprising:

one first medical imaging device;

one second medical imaging device;

10 a position measuring system comprising at least the following: a position sensing controller and at least one first position measuring component at a known position with respect to said first medical imaging device and second position measuring component at a known position with respect to said second medical imaging device;

15 a data processor for receiving data from the position sensing controller for calculating the relative position of said second medical imaging device and/or relative position of the scanning plane/volume produced by said second medical imaging device with respect to said first medical imaging device and/or with respect to the scanning plane/volume produced by said first medical imaging device, said data processor displaying on at least one display screen said calculation in a cooperative way to the medical operator.

20

18. Apparatus according to claim 17 where the at least one display screen is one.

19. Apparatus according to claim 17 where said first and said second medical imaging device operate simultaneously and/or intermittently.

20. Apparatus of claim 17 where said first and said second medical imaging devices are one of the group X-Ray, CT, MRI, ultrasound or endoscope.
21. The apparatus of claim 17 where the position measuring system is from the group: magnetic, optic, acoustic, inertial, fiber optic or a combination of the above.
- 5 22. Apparatus of claim 17 where the step of sensing the position of said second medical imaging device with respect to said first medical imaging device is performed by means of wired or wireless communication.
23. Apparatus according to claim 17 where said at least one first position measuring component is attached onto said first medical imaging device.
- 10 24. Apparatus according to claim 17 where said at least one second position measuring component is attached onto said second medical imaging device.
25. Apparatus according to claim 17 where said at least one first position measuring component and said at least one second position measuring component work in operative communication.
- 15 26. Apparatus according to claim 17 where said calculation is based on the direct measurement of the relative position between said at least one first position measuring component and said at least one second position measuring component.
27. Apparatus according to claim 17 where said calculation is based on directly measuring the position of said at least one first position measuring component with to
20 said at least one second position measuring component.

28. Apparatus according to claim 17 where said position measuring system
additionally comprises at least one third reference position measuring component being
placed at a first reference location;

5 said at least one third position measuring component being in operative communication with said at least one first position measuring component and said at least one second position measuring component and enabling to calculate the relative position between them.

29. Apparatus according to claim 37 where the scanned plane/volume produced by
said at least one first medical imaging device is correlated and/or fused by image
processing tools with the scanned plane/volume produced by said at least one second
medical imaging device.

30. Apparatus according to claim 17 and further comprising the step of correlating the calculated position of at least one target or the relative position between several targets/points in order to assess internal anatomic movements between different stages of a medical procedure.

31. Apparatus according to claim 17 further comprising the step of indicating to said position sensing system the position of a target by marking said target on said at least one display screen or by automatic recognition from the image..

32. Apparatus according to claim 17 further comprising the step of indicating to
20 said position sensing system the position of said reference plane/volume by marking
said reference plane/volume on said at least one display screen.

33. Apparatus according to any of the claims 31-32, where the position of the said at least one second medical imaging device is calculated with respect to said target and/or said reference plane/volume.

34. Apparatus according to claim 17 where the position of the scanning plane/volume produced by the said at least one second medical imaging device is calculated with respect to said target and/or said reference plane/volume.

35. Apparatus according to claim 17 and further comprising the step of indicating on said at least one display screen the actual progressive motion of said at least one second medical imaging device towards said target and/or reference plane/volume.

36. Apparatus according to claim 17 and further comprising the step of indicating on said at least one display screen the deviation of said at least one second medical imaging device or scanning plane/volume produced by said at least one second medical imaging device from said target and/or from said reference plane/volume.

37. Apparatus according to claim 17 and further comprising the step of correlating the calculated position of at least one target or the relative position between several targets/points in order to assess internal anatomic movements between different stages of a medical procedure.

38. Apparatus enabling to guide an invasive tool towards a target visible by endoscope means, in a free of predefined mechanical constraints cooperative operation comprising:

an endoscopic imaging device;
an invasive tool;

5

a position measuring system comprising at least the following: a position sensing controller and at least one first position measuring component at a known position with respect to said endoscope imaging device and second position measuring component at a known position with respect to said invasive tool;

10

a data processor for receiving data from the position sensing controller for calculating the relative position of said invasive tool with respect to the image(s) produced by said first medical imaging device, said data processor displaying on at least one display screen said calculation in a cooperative way to the medical operator.



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(54) Title: APPARATUS AND METHODS FOR MEDICAL DIAGNOSTIC AND FOR MEDICAL GUIDED INTERVENTIONS AND THERAPY			
(57) Abstract			
<p>Systems and methods for medical diagnostic and for medical guided interventions using multiple imaging systems are introduced. These systems and methods recognize the need for a relatively simple and modular way of combining information available from two or more medical imaging apparatus in medical diagnosis and in image guided surgery and therapy. Particularly these methods enable to minimize mechanical constraints involved in a cooperative operation of several medical imaging devices. The apparatus and methods introduced in the present invention enable to measure the relative position between different medical imaging devices and between the image planes and/or image volumes produced by them by means of using a position measuring system based with attachable position measuring components. This facilitates image fusing when images of the same plane/volume are available from different medical imaging systems. Additionally/alternately it enables to position a second medical imaging device over a desired area/volume according to information received from the image produced by the first medical imaging device.</p>			

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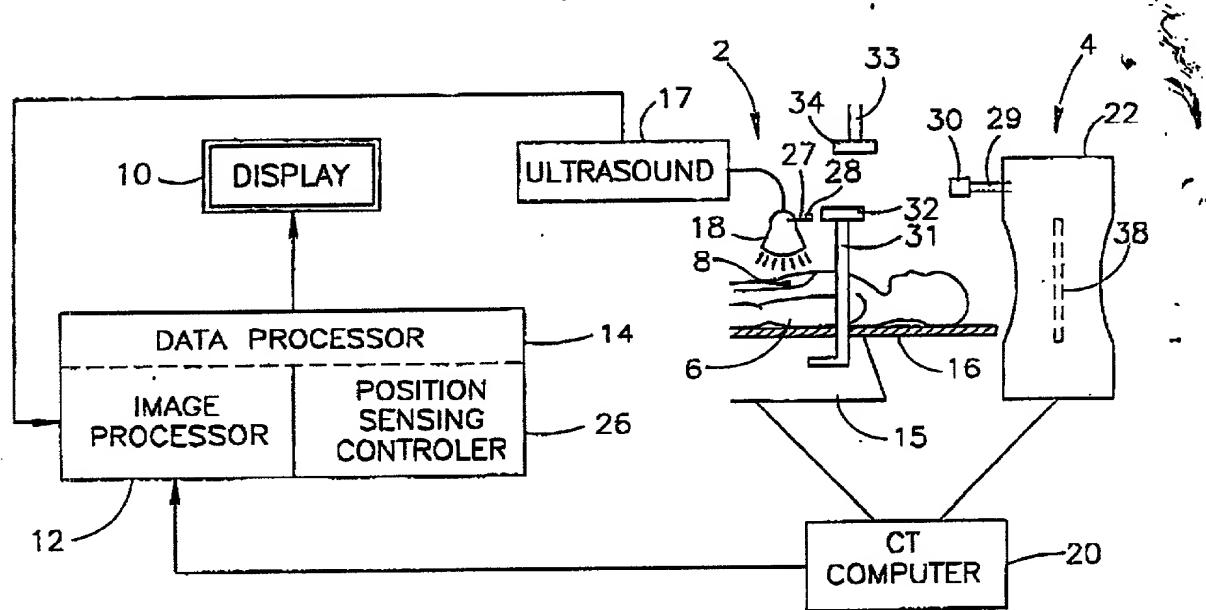


FIG.1A

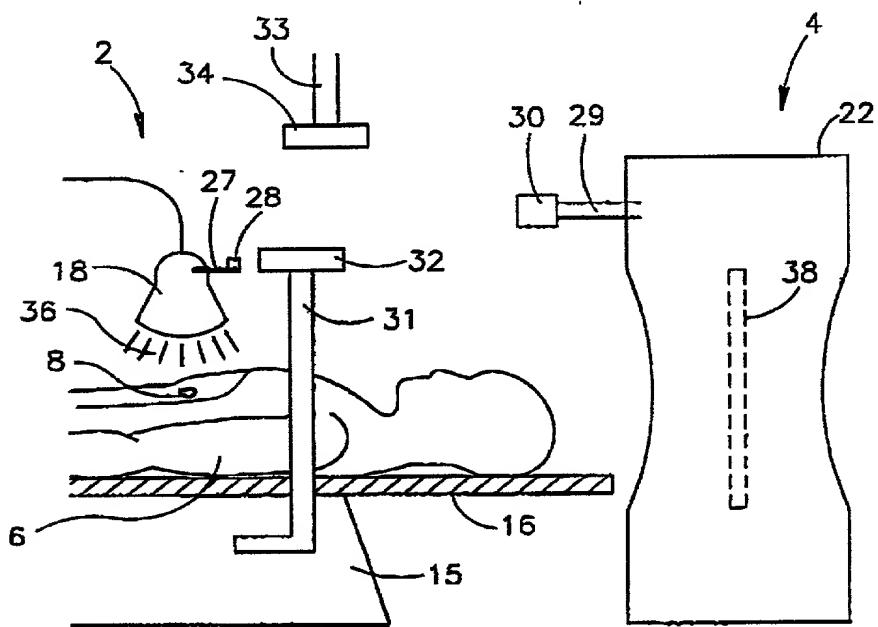


FIG.1B

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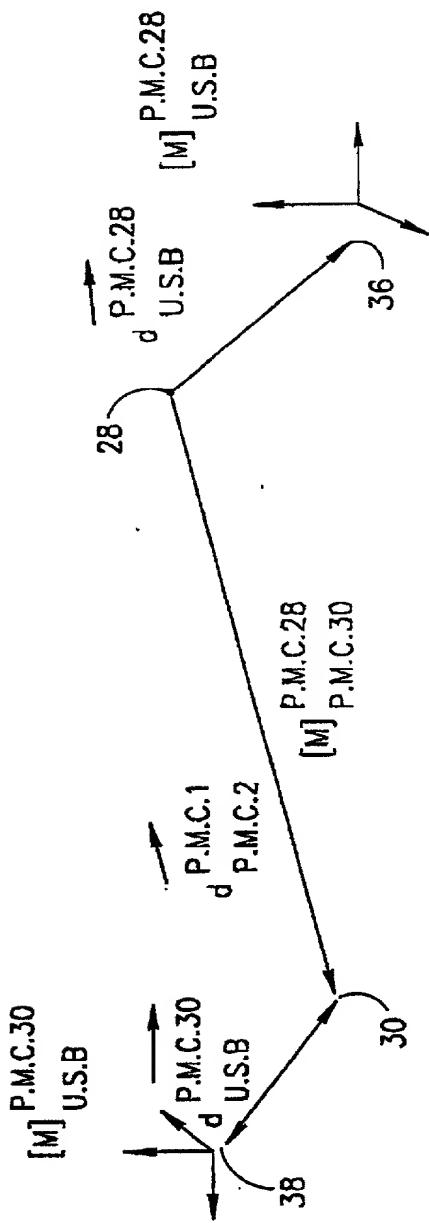


FIG.2A

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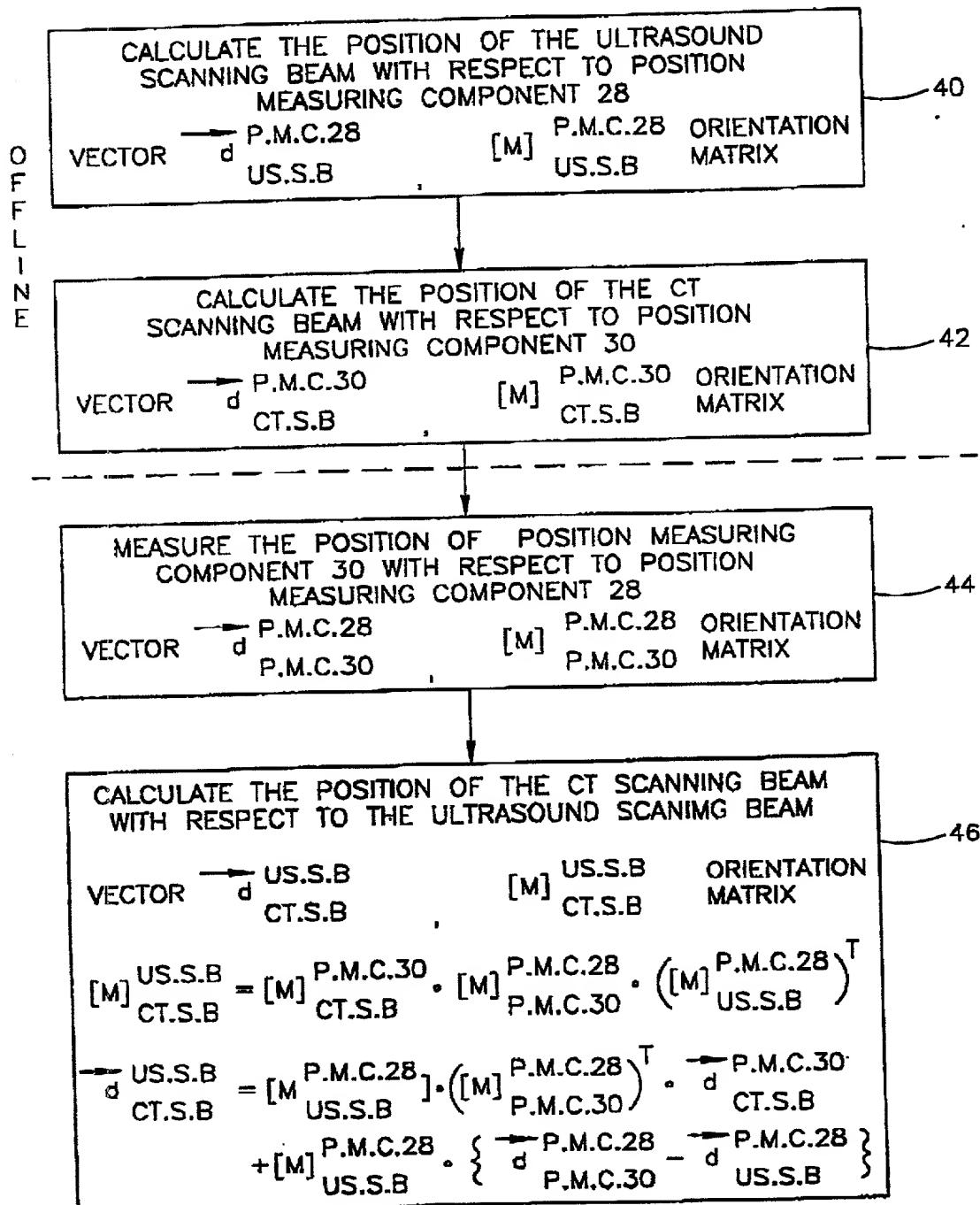


FIG.2B

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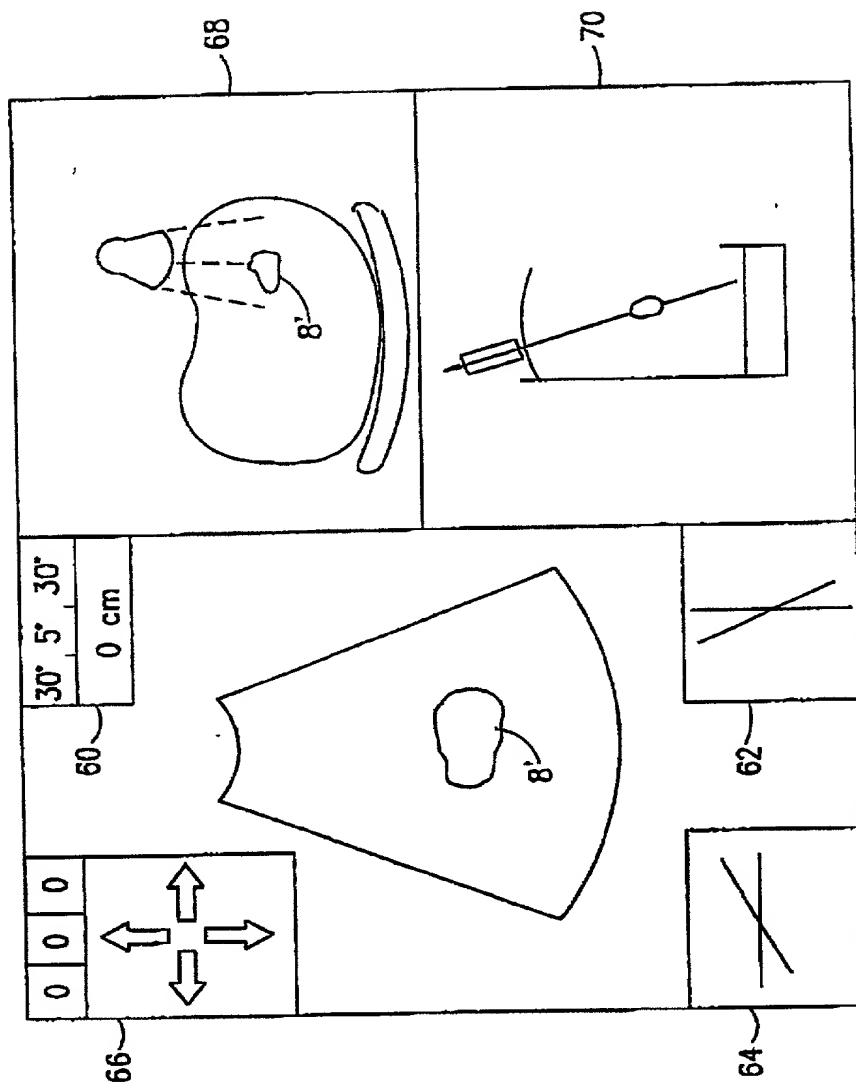


FIG. 3

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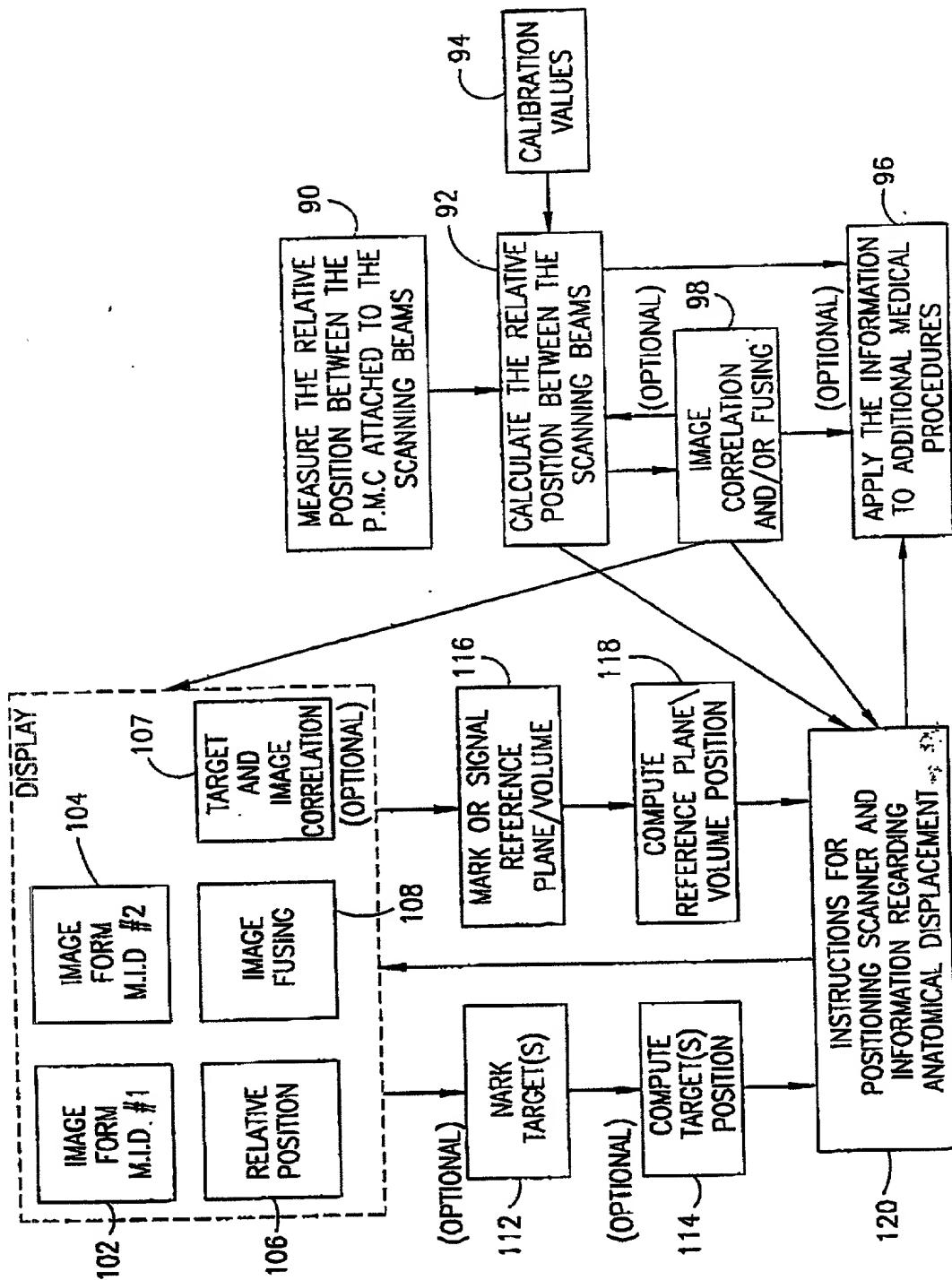


FIG. 4

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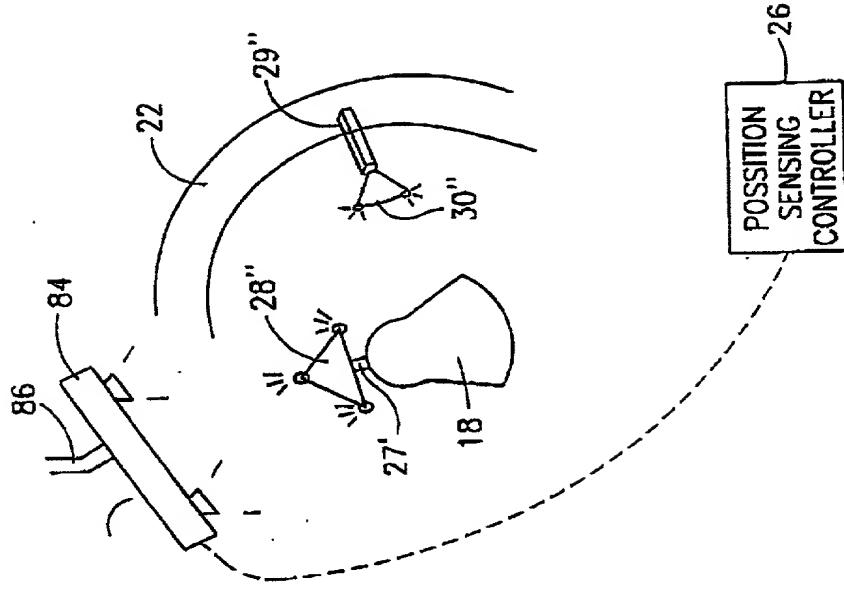


FIG. 5B

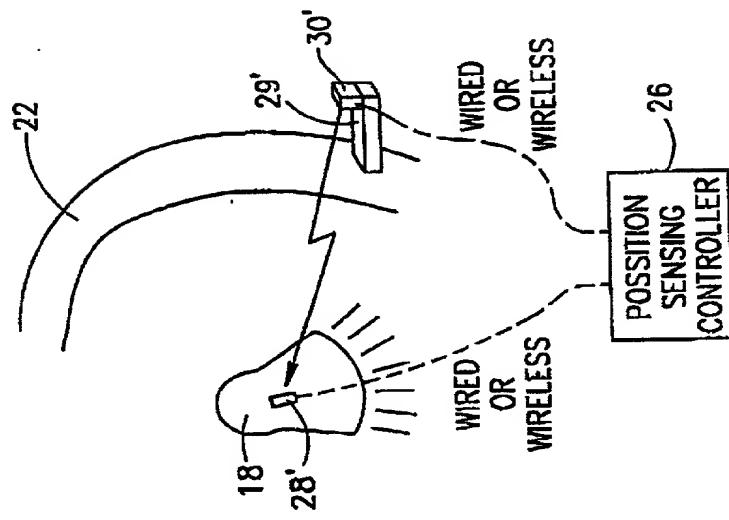


FIG. 5A

SUBSTITUTE SHEET (RULE 26)

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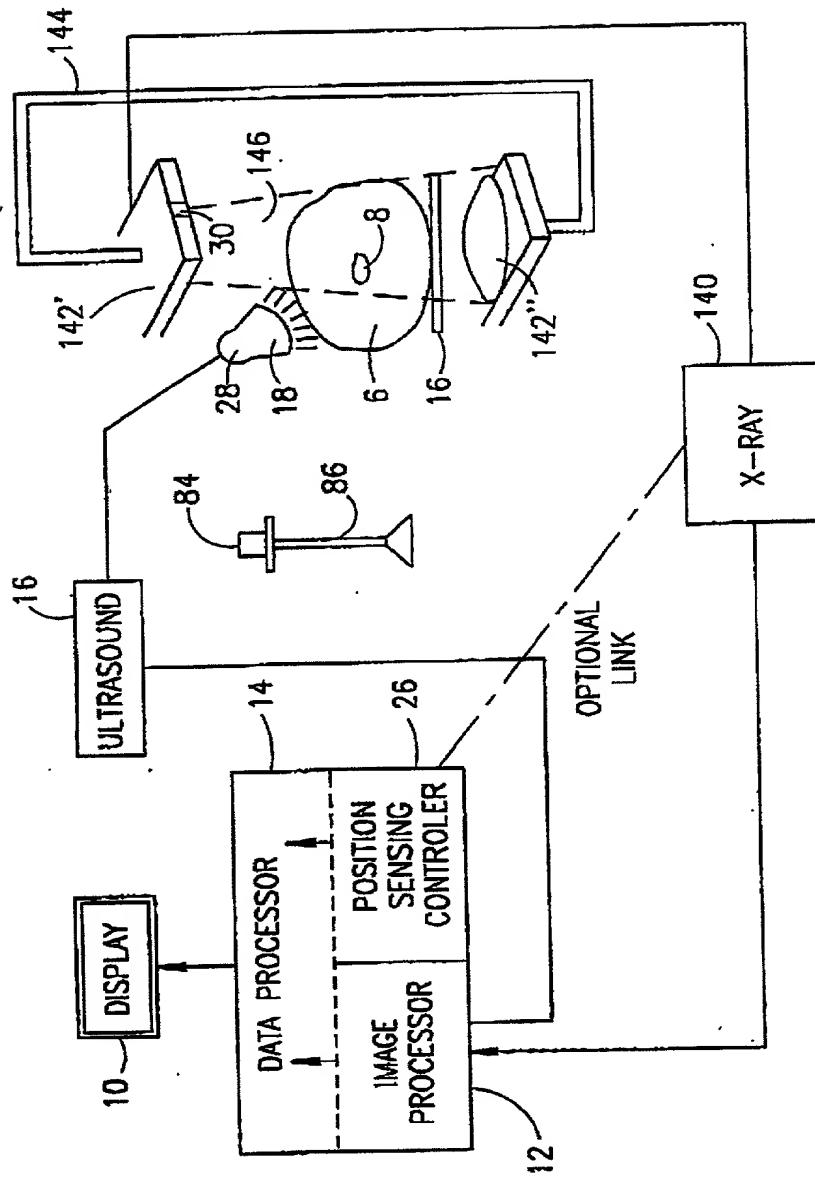


FIG. 6

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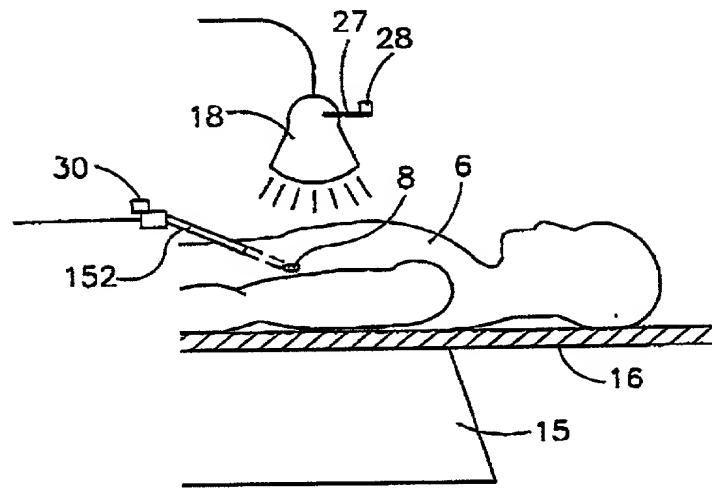


FIG. 7A

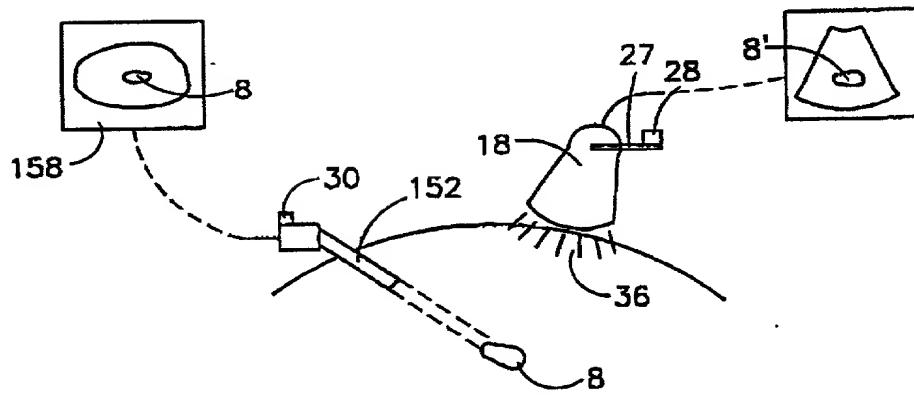


FIG. 7B



DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below under my name.

I believe that I am an original, sole and or joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled

APPARATUS AND METHODS FOR MEDICAL DIAGNOSTIC AND FOR MEDICAL GUIDED INTERVENTIONS AND THERAPY

the Specification of which



is attached hereto
 was filed on **March 30, 2000**
 as United States Application Number or PCT International
 Application No. **PCT/IL00/00202**
 and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified Specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, 1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any provisional application filed in the United States in accordance with 35 U.S.C. §1.119(e), or any application for patent that has been converted to a Provisional Application within one (1) year of its filing date, or any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

PRIOR FILED APPLICATION(S)

<u>APPLICATION NUMBER</u>	<u>COUNTRY</u>	<u>(DAY/MONTH/YEAR FILED)</u>	<u>PRIORITY CLAIMED</u>
60/127,267	US	31 March 1999	Yes
PCT/IL00/00202	PCT	30 March 2000	Yes

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application listed below, and, insofar as the subject matter of each of the claims of this application is not disclosed in any prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined

in Title 37, Code of Federal Regulations, §1.56(a), which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

APPLICATION NO.	FILING DATE (DAY/MONTH/YEAR)	STATUS - PATENTED, PENDING, ABANDONED
PCT/IL00/00202	30 March 2000	PENDING, ABANDONED

I hereby appoint as my attorney(s) and agent(s) Heidi M. Brun (Agent, Registration No. 34,504), or Daniel J. Swirsky (Agent, Registration No. 45,148) or Mark S. Cohen (Attorney, Registration No. 42,425) or Rochel L. Abboudi (Agent, Registration No. 44,490) or Suzanne Erez (Agent, Registration No. 46,688) or Vladimir Sherman (Attorney, Registration No. 43,116) or David Klein (Agent, Registration No. 41,118) or Adele Marcus (Agent, Registration No. 47,769) or Caleb Pollack (Attorney, Registration No. 37,912) said attorney(s) and agent(s) with full power of substitution and revocation to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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DATE 15-4-01

2-60
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COUNTRY OF CITIZENSHIP: Israel ISX

FULL POST OFFICE ADDRESS: same

SIGNATURE OF INVENTOR Paltiel

DATE 15 - 4 - 02